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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	)	CRIM. NO. 1:20-cr-244
	)	
v.	)	
	)	(JUDGE Jones)
JONATHAN CLARK BAIRD,	)	
	)	
Defendant.	)	UNDER SEAL

INDICTMENT

COUNT 1

CONSPIRACY TO DEFRAUD THE FOOD AND DRUG ADMINISTRATION, AN AGENCY OF THE UNITED STATES (18 U.S.C. § 371)

THE GRAND JURY CHARGES:

INTRODUCTION

At times material to this Indictment:

1. Defendant Jonathan Clark Baird ("Baird") of Louisville, Kentucky, was an attorney licensed to practice law in the Commonwealth of Kentucky. On his law firm website, Baird held himself out as focusing on steroid and nutritional supplements law.

2. From in or about December 2011, to in or about December 2014, Baird conspired with two Internet-based businesses, Total

Trading LLC and L and P Trading LLC, to defraud the United States of, and concerning, its governmental functions and rights. In particular, Baird agreed to use his knowledge of steroid laws, nutritional supplement laws and the FDA's regulatory and enforcement practices to instruct these companies on the methods to use to interfere and obstruct the United States Food and Drug Administration enforcement and regulatory oversight, including instructing his co-conspirators on the steps to be taken to fraudulently conceal the true nature of their illegal sale of prescription drugs from the FDA.

TOTAL TRADING, LLC

3. Thomas Keightly ("Keightly"), a resident of Lebanon County, Pennsylvania owned and operated two illegal drug manufacturing and distribution facilities in Lebanon County. Keightly owned and operated these facilities under the company name Total Trading, LLC.

4. Keightly used the Total Trading website, to advertise and sell to customers nationwide prescription drugs without prescriptions. Keightly also manufactured many of the same drugs without the required FDA approval and oversight.

5. The drugs Keightly sold were known to counter the effects of anabolic steroids and many of Keightly's customers were members of the bodybuilding community who illegally used anabolic steroids.

L AND P TRADING, LLC

6. Dominic Pileggi ("Pileggi") and Paul Leix ("Leix"), residents of Illinois, owned and operated L and P Trading, LLC ("L and P") also located in Illinois.

7. Pileggi and Leix used the L and P website to advertise and sell to customers nationwide prescription drugs without prescriptions. Pileggi and Leix also manufactured many of these drugs without the legally required FDA approval and oversight.

8. In addition to their Internet-based sales, Pileggi and Leix also shipped to Keightly drugs and chemicals used to make the drugs. L and P shipped these drugs and chemicals to Lebanon, Pennsylvania.

9. Like Keightly, the drugs Pileggi and Leix manufactured, advertised and sold were known to counter the effects of anabolic steroids use and many of Pileggi and Leix's customers were members of the bodybuilding community who use anabolic steroids.

THE FOOD AND DRUG ADMINISTRATION

10. "The United States Food and Drug Administration ("FDA") was the federal agency charged with the responsibility of protecting the health and safety of the American public by assuring, among other things, that drugs sold to humans were safe and effective for their intended uses and bore labeling containing information that was accurate and sufficient for the product's safe use. FDA's responsibilities included regulating the manufacture, distribution, and labeling of all drugs shipped or received in interstate commerce. FDA was responsible for, among other things, enforcing the Federal Food, Drug, and Cosmetic Act (FDCA), Title 21, United States Code, Section 301, et seq.

11. FDA's responsibilities included inspecting facilities where drug products were manufactured, labeled, packaged and held; examining the records at such facilities to determine whether the drugs were manufactured under conditions whereby their quality could be assured; and, where appropriate, preventing products that were unapproved for marketing, or were improperly packaged or labeled from reaching the marketplace.

12. Under the FDCA, the term "drug" included any article and component of any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or an article (other than food) intended to affect the structure or any function of the body of man or other animals. 21 U.S.C. § 321(g)(1)(B), (C),(D). Some of the drugs regulated under the FDCA were "prescription drugs." Prescription drugs were those drugs, which, "because of their toxicity or other potential harmful effects, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs," or which were required to be administered under the supervision of a licensed medical practitioner as a condition of FDA approving any such drug to be allowed on the market. 21 U.S.C. § 353(b)(1)(A) and (B).

13. The FDCA provided that before a new drug can be distributed in interstate commerce, its manufacturer must obtain FDA approval of a New Drug Application, an Abbreviated New Drug Application (for generic drugs), or an Investigational New Drug Application (for drugs being researched in humans). 21 U.S.C. §§

355(b),(j), and (i). To receive approval to market a drug, the manufacturer must have submitted information showing that the new drug is safe and effective for its intended use, 21 U.S.C. § 355(b)(1); 21C.F.R. § 314.50, or for generics to show that it is bioequivalent to the pioneer (brand name) drug. 21 U.S.C. § 355(j).

14. The introduction or delivery for introduction or causing the introduction or delivery for introduction into interstate commerce of any misbranded drug was prohibited. 21 U.S.C. § 331(a). "Misbranding" encompassed dispensing a prescription drug without a valid prescription. 21 U.S.C. § 353(b)(1).

15. A drug was also misbranded where its labeling was false or misleading in any particular, 21 U.S.C. § 352(a); where its labeling did not bear adequate directions for use, 21 U.S.C. § 352(f)(1); or where the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not registered with the Secretary of Health and Human Services, 21 U.S.C. § 352(o).

16. As mentioned above, a drug is misbranded unless its labeling bears adequate directions for its use, which is further defined by regulation as "directions under which the layman can use a drug safely

and for the purposes for which it is intended." 21 C.F.R. § 201.5. Because prescription drugs by definition can only be safely used under the supervision of a licensed medical practitioner, they must qualify for an exemption to this labeling requirement to be legally distributed in interstate commerce. The exemption is set forth in 21 C.F.R. § 201.100, and it states that a prescription drug will be exempt from the requirement of 21 U.S.C. § 352(f) (that its labeling adequate directions for use) if all the conditions of the exemption are met, including: (1) that the drug be in the possession of person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or (2) in the possession of a retail, hospital, or clinic pharmacy regularly and lawfully engaged in dispensing prescription drugs; or (3) in the possession of a practitioner licensed by law to administer or prescribe such drugs; and (4) the drug is to be dispensed pursuant to a valid prescription. In addition, if the drug is one required under the FDCA to have an approved application prior to distribution, the drug must bear the FDA-approved labeling.

17. As mentioned above, a drug was misbranded if it was manufactured in an unregistered manufacturing facility. 21 U.S.C. §

352(o). Owners and operators of any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs must annually register with FDA their names and places of business, the unique facility identifier of each establishment, and a point of contact e-mail address. 21 U.S.C. § 360(b)(1). The establishment also must list the drug products it is manufacturing. 21 U.S.C. § 360(j). This information provided by registration and listing alerts FDA that drug products are being manufactured and triggers the need for an inspection to assure that the drugs are in conformance with law and regulations. 21 U.S.C. § 360(h)(1).

18. Like the manufacturing of drugs, the distribution of prescription drugs was also heavily regulated in the United States. Wholesalers (drugs distributed to someone other than the ultimate consumer) must be licensed, 21 U.S.C. § 353(e), as must dispensers and prescribers. 21 U.S.C. § 353(b); 21 C.F.R. § 201.100.

THE DRUGS L AND P AND TOTAL TRADING UNLAWFULLY MANUFACTURED, MARKETED AND SOLD ON THE INTERNET

19. Peptides" were chemical compounds containing two or more amino acids linked by the carboxyl group of another. Due to their

toxicity or potential for harmful effect, peptides could only safely be used under the supervision of a licensed medical practitioner.

20. There was an illegitimate market for peptides among body builders and others who engaged in weight training, since it was believed that the use of these substances enhanced muscle development.

21. Clenbuteral was a prescription drug, which is not FDA-approved for any human use, but is approved for veterinary use. Clenbuteral is used illegally by bodybuilders for its alleged fat burning properties.

22. Tadalafil is a prescription drug and the active ingredient of Elli Lilly's FDA-approved erectile dysfunction drug, Cialis. There are no approved generic drugs containing Tadalafil.

23. Sildenafil Citrate is a prescription drug and the active ingredient in Pfizer Corporation's FDA-approved erectile dysfunction drug Viagra. There are no approved generic erectile dysfunction drugs containing sildenafil citrate.

24. Letrozole is a prescription drug and is the active ingredient in Novartis Pharmaceutical's FDA-approved breast cancer drug

Femara. There are approved generic drugs containing letrozole, but defendant is not approved to manufacture it.

25. Tamoxifen is a prescription drug and is the active ingredient in Astrazeneca's breast cancer drug Nolvadex, and Midatech Pharma's Soltamox. There are approved generic drugs containing tamoxifen, but defendant is not approved to manufacture it.

26. Tamoxifen and letrozole are used by body builders and other athletes to counter the effects of steroid abuse, specifically a condition called gynecomastia, where a male's breast tissue becomes enlarged.

27. Clomiphene citrate is a prescription drug and the active ingredient in various FDA-approved drugs used to treat infertility, e.g., Sanofi Aventis's drug Clomid. There are approved generic drugs containing clomiphene citrate, but defendant is not approved to manufacture it. Clomiphene citrate is used by male body builders and other male athletes to self-treat for gynecomastia.

28. Anastrozole is a prescription drug and the active ingredient in Astrazeneca's breast cancer drug Arimidex. There are approved generic drugs containing Anastrozole, but defendant is not approved to

manufacture it. Anastrozole is used by male body builders and other male athletes to self-treat for gynecomastia.

29. Exemestane is a prescription drug and the active ingredient in Pharmacia and Upjohn's FDA-approved breast cancer drug Aromasin. There are approved generic drugs containing exemestane; however, defendant is not approved to manufacture it. Extemestane is used by male body builders and other male athletes to self-treat for gynecomastia.

30. Rimonabant was developed by Sanofi-Aventis to treat obesity. It was approved as a prescription drug in Europe, but was later withdrawn from the market due to potentially serious side effects. It has never been approved in the United States.

THE CONSPIRACY

31. From in or about November 2011, through in or about December 2014, in the Middle District of Pennsylvania and elsewhere, the defendant,

JONATHAN CLARK BAIRD

Keightly, Leix and Pileggi knowingly and willfully conspired and agreed together and with each other, and with others persons known and

unknown to the Grand Jury to defraud the Food and Drug Administration, an agency of the United States of America, of its governmental functions and rights, in that Baird, Keightly, Leix and Pileggi agreed to obstruct, impede, and interfere with the FDA's governmental functions and rights.

MANNERS AND MEANS

32. Keightly, Pileggi and Leix's illegal businesses generated revenue from the internet sale of drugs. In order to obtain and maintain a nationwide customer base, Keightly, Pileggi and Leix advertised drugs on their respective company websites.

33. Keightly, Pileggi and Leix's businesses were dependent on the ability to list drugs on the websites where customers could order the drugs and make payment with credit card.

34. Baird specifically informed Keightly, Pileggi, and Leix that federal Law enforcement regulators, including the FDA monitored websites that advertised and sold prescription drugs.

35. In 2011, Keightly consulted with a licensed New York attorney about Keightly's sale of prescription drugs without prescriptions. This attorney advised Keightly his conduct was illegal.

36. Keightly then learned from Baird's law firm website that Baird, a licensed attorney in Kentucky, focused on steroid and nutritional supplement laws.

37. Keightly consulted with Baird and told him about the true nature of his business practices, specifically the internet sale of prescription drugs without prescriptions. Baird told Keightly there were steps he should take to avoid detection from the FDA that monitored internet businesses like Keightly's. Baird instructed Keightly on the use of the research only ruse. Baird also directed Keightly on measures to ensure the business practices did not undermine the disclaimer. In particular, Baird instructed Keightly to ensure his website contained the false statement that the drugs sold on the website were for research purposes only and not for human use.

38. Keightly and Baird signed a retainer and Baird agreed to assist Keightly with the sale of the drugs in a manner that would fraudulently conceal the true nature of Keightly's business from the FDA and other federal regulatory authorities.

39. Beginning in 2011, and through 2013, Baird reviewed the Total Trading business model, including the business website.

40. Beginning 2011, Baird was aware that Keightly through his business, Total Trading advertised and sold on the internet prescription drugs without prescriptions.

41. In addition to the illegal internet sale of prescription drugs Leix and Pileggi also had an ongoing business relationship with Keightly. Leix, Pileggi and Keightly agreed to share sources for the chemicals and drugs they sold. In addition, when they ran short on supplies they agreed to share supplies so that their sales could resume unimpeded. On occasions Keightly, Leix and Pileggi would also ship drugs to their respective customers when one business was short of a particular drug. As a result of this business relationship and the knowledge that Pileggi and Leix were also involved in the illegal sale on the internet of prescription drugs, Keightly recommended that Leix and Pileggi hire Baird to assist them in avoiding federal regulatory scrutiny and enforcement actions.

42. Leix and Pileggi, like Keightly retained Baird to review the L and P's business model, including the company website and instructed Leix and Pileggi on how to fraudulently conceal the true

nature of the business activities from the FDA and interfere with the FDA's enforcement actions.

43. Leix and Baird consulted and then retained Baird. From the time Baird was retained by Leix and Pileggi, Baird was aware that Leix and Pileggi through their business L and P were advertising and selling on the internet prescription drugs for human use with our prescriptions.

44. In accordance with his agreement with Leix and Pileggi, Baird provided Leix and Pileggi with specific directions on how to conceal their illegal activity from the FDA and thus defeat the FDA's regulatory oversight and enforcement actions.

45. Baird was aware the payments he received from Keightly, Leix and Pileggi were proceeds of their illegal prescription drug sales.

OVERT ACTS

In furtherance of the conspiracy and to effect the object of the conspiracy, the following over acts were undertaken:

46. On or about December 20, 2011, Keightly signed a retainer for Baird's legal services and forwarded from the retainer from Lebanon County, Pennsylvania to Baird in Kentucky.

47. On or about October 11, 2012, Keightly signed a second retainer for Baird's legal services and forwarded the retainer from Lebanon County, Pennsylvania to Baird in Kentucky.

48. Beginning in or about 2012, Baird reviewed Keightly's business website and told him that the website should always include the disclaimer that the drugs and chemicals sold on Keightly's website were for research purposes only and not for human use.

49. In or about 2013, Baird also reviewed the website and its advertising. Baird instructed Keightly not to advertise on bodybuilding websites because such advertisements would lead to the FDA's detection that Keightly was marketing and selling prescription drugs for human use.

50. In 2013, Baird instructed Keightly on how to respond to customer complaints in manner that would not reveal Keightly was aware his customers were using the drugs he was selling.

51. In or about 2013, Baird requested that Keightly send to Baird drugs Keightly was selling in order that Baird could inspect the packaging to ensure it was consistent with the research purposes only ruse designed to fraudulently conceal the illegal activity from the FDA.

57. On May 28, 2014, a letter from J. Clark Baird to L and P Trading LLC to discuss Leix's business and Baird's representation.

58. On April 6, 2013, Leix mailed a package of prescription drugs to Baird.

59. On May 29, 2013, Leix mailed a package of prescription drugs to Baird.

60. On July 28, 2013, Leix mailed a package of prescription drugs to Baird.

61. On September 17, 2013, Leix mailed a package of prescription drugs to Baird.

62. On November 5, 2013, Leix mailed a package of prescription drugs to Baird.

63. On December 16, 2013, Leix mailed a package of prescription drugs to Baird.

64. On January 29, 2014, Leix mailed a package of prescription drugs to Baird.

65. On November 28, 2014, Leix mailed a package of prescription drugs to Baird.

52. Beginning in 2013, Baird reviewed Leix and Pileggi's website and instructed them on how to avoid FDA scrutiny and detection.

53. Beginning in or about June 2012, Baird instructed Leix not to advertise on bodybuilding websites because such advertisements would undermine the for research purposes only ruse.

54. On October 17, 2012, a package was sent from L and P Trading LLC to J. Clark Baird, Republic Plaza, 200 South 7th Street, Suite 504, Louisville, KY 40202-2739. The package confirmation number was 9471011201080788488115 and the cost of the shipment was $17.75.

55. On December 10, 2012, package was sent from L and P Trading LLC to Clark Baird, Republic Plaza, 200 South 7th Street, Suite 504, Louisville, KY 40202-2739. The package confirmation number was 9405511201080004930109 and the cost of the shipment was $5.15.

56. On December 16, 2013, Harris Bank – L and P Trading, LLC check number 1608 made payable to Jonathan Clark Baird in the amount of $5,000.00. The memorandum section of the check lists "Retainer".

66. On or about April 29, 2016, in a text message Baird asked Leix if federal agents had contacted him with questions about Baird.

67. On or about April 29, 2016, in a text message Baird told Leix if he believed Keightly was speaking to federal agents about Baird.

All in violation of Title 18, United States Code, Section 371.

A TRUE BILL

[redacted]

FOREPERSON, GRAND JURY

DAVID J. FREED
UNITED STATES ATTORNEY

By: _____
JOSEPH J. TERZ
ASSISTANT U.S. ATTORNEY

9/30/20
DATE